Remarks

The Application has been reviewed in light of the Official Action of October 26, 2010. Claims 25-38, 40-48, 50 and 52 are pending in the Application.

The Examiner has rejected Claim 50 under 35 U.S.C. 102(b) as being anticipated by Lewis, Lon (Feeding and Care of the Horse second edition; 1995, Blackwell Publishing Professional, Ames, Iowa). (Referred to herein as "Lewis 2005.") The Examiner has rejected claims 25-38, 40-48, 50 and 52 under 35 U.S.C. 103, as being obvious over Lewis 2005, Lewis, Lon (Equine Clinical Nutrition Feeding and Care; 1995, Williams & Wilkins, Media, Pa) (Referred to herein as "Lewis 1995"), Parsons, HS., (Care and Management of the Older Horse; 2001, Trafalgar Square Publishing, North Pomfret, Vermont), and Weese et al. (Abstract; J. Am. Vet. Med. Assoc. 1999, 214(2), 229-32).

As an initial matter, Applicant reiterates its objection to the Examiner's reliance on the Lewis 2005 publication because this document has a copyright date of 2005 and as a result is not prior art. To the extent the Examiner believes that a 1995 publication contains the same disclosure, then the Examiner needs to provide copies of that document.

Moreover, Applicant respectfully submits that claims 25-38, 40-48, 50 and 52 are not anticipated nor obvious in view of these references.

With respect to liver disease, Lewis 2005 teaches that "[a] diet for horses that meets the desired criteria for liver disease is one consisting of one-half milo or corn..." Lewis 2005 also teaches that an unlimited amount of legume forage can be provided in

the form of alfalfa or a lower-protein grass forage. Finally, Lewis 2005 teaches that the diet should be "low in, or at least not contain added, fat or salt."

Parsons teaches that a horse with liver disease should "avoid high-protein feeds" and that the horse should be fed "late-cut hay (which is generally lower in protein)." (Parsons, p. 236). Moreover, Parsons teaches "[i]f in doubt, therefore, maintain your horse on a solely high fibre diet..." (Parsons, p. 237).

With respect to kidney failure, Lewis 2005 teaches that a "diet low in protein, phosphorus, and calcium can be provided by feeding a grass forage" and optionally including a cereal grain.

Weese et al. does not address treating a horse with an energy deficiency due to hepatic dysfunction, renal dysfunction, or digestive tract disease.

Applicant respectfully submits that claims 25 and 50 are not obvious in view of these references, because these references fail to disclose or remotely suggest administering to a mammal with an energy deficiency due to hepatic dysfunction, renal dysfunction, or digestive tract disease a composition or feed program with less than 3% fat and whey powder.

Lewis 2005 teaches administering "one-half milo or corn" and "alfalfa or a lower-protein grass forage." Parsons teaches avoiding "high-protein feeds" and feeding "late-cut hay." These references fail to demonstrate that one skilled in the art would recognize that a mammal with an energy deficiency due to hepatic dysfunction, renal dysfunction, or digestive tract disease can be treated by administering a composition or feed program with less than 3% fat and whey powder. *KSR Int'l Co. v. Teleflex, Inc.*, 127

S.Ct. 1727, 1741 (2007) ("it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does"). Further, given the restrictions on the diets recommended by both references, and the teaching to limit the administration of protein, it is clear that these references would lead one skilled in the art away from the claimed invention. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 USPQ 303, 311 (Fed. Cir. 1983) (noting that it is improper to consider "the references in less than their entireties" and disregard "disclosures in the references that diverge from and teach away from the invention at hand")

Moreover, these references fail to disclose or recognize the therapeutic benefits of administering a composition or feed program with less than 3% fat and whey powder or deficiency with the methods they propose. The present Application discloses:

> When supplying protein requirements, consideration must be given to quality as well as quantity. Without high quality protein, a normally adequate quantity can still result in a mammal that is protein starved. This will lead to continued catabolism of muscle to meet the protein needs, especially in the face of disease. High quality protein also reduces the amount of work required by the liver and kidneys, which is critical in many disease states.
> ...
> In some embodiments, whey powder is the preferable bulking agent of the protein component for it has a low fat content and high protein content.
> ...
> The protein found in whey is of extremely high biological value. Whey is easy for the body to digest and utilize and effective as a protein source in the face of very depressed hepatic function, elevated blood ammonia levels, and hepatic encephalopathy. Whey is completely soluble in water. Whey is also only 1% fat, which is optimal when providing predetermined nutraceutical compositions of the present invention.

(Application ¶¶ [0043], [0049], [0051]).

Lewis 2005 and Parsons, on the other hand, fail to recognize the potential deficiency with their methods. Namely, that the protein sources taught to be administered to a horse can still result in a horse that is protein starved. These references also fail to recognize that the administration of a composition or feed program with less than 3% fat and whey powder is an improvement because it provides a high quality protein source that reduces the amount of work required by the liver and kidneys. Simply because whey is known does not render the claims obvious because there is no teaching or evidence that own skilled in the art would recognize that whey could or should be included in a composition or feed program with less than 3% fat that is administered to a mammal with hepatic dysfunction, renal dysfunction, or digestive tract disease.

Respectfully submitted,

/Wesley W. Whitmyer, Jr./

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